

The opinion in support of the decision being entered
today was not written for publication and
is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL J. BIERMANN,
JACK C. ROBERTS and AMY A. CORVELLI

Appeal No. 2001-0611
Application No. 08/742,733

ON BRIEF

Before ABRAMS, STAAB, and NASE, Administrative Patent Judges.
STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final
rejection of claims 11-23 and 26-44, all the claims pending in
the application.

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Appellants' invention pertains to an orthopedic implant for replacing a missing or diseased portion of bone. A further understand of the invention can be derived from a reading of exemplary claims 11 and 26, reproduced below:

11. An orthopedic implant for replacing a missing or diseased portion of bone, the implant comprising:

a thermoplastic polymer having an elastic modulus approximating the elastic modulus of bone; and

a biocompatible material partially embedded in the surface of the implant.

26. An intramedullary implant for replacing a missing or diseased portion of bone comprising:

a first piece comprising a first end for insertion into the medullary cavity of a bone and a second end having a protruding member thereon;

a second piece comprising a first end for insertion into the medullary cavity of a bone and a second end having a cavity formed therein for receiving the protruding member on the second end of the first piece; and

means for resisting rotation between the first and second pieces;

wherein the rotation resisting means comprises a flute on the protruding member and a corresponding fluted opening in the cavity.

The references cited in the final rejection are:

Goble et al. (Goble)	5,417,692	May 23, 1995
Moumene et al. (Moumene)	5,443,513	Aug. 22, 1995
Bokros	4,038,703	Aug. 02, 1977

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Claims 11-23, 43 and 44 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 11-17, 43 and 44 stand rejected under 35 U.S.C. § 103 as being unpatentable over Moumene in view of Bokros.

Claims 26-33 stand rejected under 35 U.S.C. § 103 as being unpatentable over Goble.

Claims 34-37 stand rejected under 35 U.S.C. § 103 as being unpatentable over Goble in view of Bokros.

Claims 38-42 stand rejected under 35 U.S.C. § 103 as being unpatentable over Goble in view of Moumene.

Claims 18-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Goble in view of Moumene and Bokros.

Reference is made to appellants' main and reply briefs (Paper Nos. 14 and 16) and to the second final rejection and examiner's answer (Paper Nos. 11 and 15) for the respective positions of appellants and the examiner regarding the merits of these rejections.

The § 112, second paragraph, rejection

Considering first the rejection of claims 11-23, 43 and 44 under 35 U.S.C. § 112, second paragraph, the examiner maintains that the claims are indefinite because the term "the surface" (claim 11, line 7; claim 43, line 5; claim 44, line 6) lacks a

proper antecedent basis. Appellants "concur in the Examiner's rejection under 35 USC 112, second paragraph, and will offer an appropriate amendment should the Board reverse any of the Examiner's rejections under § 103(a) as to these claims" (main brief, page 5). In that appellants have chosen not to present any argument directed to the merits of this rejection, but have simply offered to submit "an appropriate amendment" to remedy the claim deficiency, the rejection of claims 11-23, 43 and 44 on this ground is summarily affirmed.

The § 103 rejection of claims 11-17, 43 and 44 as being unpatentable over Moumene in view of Bokros

Appellants expressly state (main brief, page 5) that the claims grouped under each rejection stand or fall together. Therefore, in accordance with 37 CFR § 1.192(c)(7), we have selected independent claim 11 as the representative claim of this group, with claims 12-17, 43 and 44 standing or falling therewith.

Moumene pertains to a composite "beam" (i.e., an orthopedic implant device) adapted for implantation within a bone that is able to support bending and torsional loading forces applied

thereto. According to Moumene (see the Abstract), the beam

is made from an elongated core formed of chopped carbon fibers embedded in a thermoplastic polymer matrix. Encasing the core is a sheath formed of carbon reinforced filament fibers embedded in the thermoplastic polymer which is wound in spiral formation around the core and molded thereto. The winding angle and the sheath thickness along the beam may be varied to vary the modulus of elasticity to match that of the cortical bone adjacent thereto.

Moumene states that "[i]f desired, the mold [for making the implant] may include a roughened surface to impart such a surface to the outer surface of the prosthesis, such as for fixation enhancement by tissue ingrowth" (column 8, lines 32-35).

Bokros relates to a prosthetic device "having an exterior surface portion of carefully controlled and uniform porosity so as to promote the ingrowth of tissue and/or bone structure and thereby create long-lasting joinder" (column 1, lines 34-37). This is accomplished through the use of helical coil metal springs secured to the exterior surface of the prosthesis. According to Bokros, "the use of helical coil springs has been found not only to provide a ready and relatively inexpensive solution to the problem but to also provide a porous surface region the porosity of which can be precisely controlled" (column 2, lines 15-19). More particularly, porosity can be controlled

by changing the wire diameter, loop diameter, amount of overlap or interleaving between adjacent springs, and by stretching the springs to change the spacing between loops (column 3, lines 7-15). The prosthetic device of Bokros can take a variety of forms. For example, the Figures 4-6 device comprises a hip joint prosthesis having one or more channels 30 formed in the exterior surface for receiving helical coil springs 32. According to Bokros, "the depth of the channels is preferably near the loop diameter of the spring; however, in specialized cases it may be appropriate to use a shallow groove or even none at all" (column 4, lines 9-12).

Based on the above reference teachings, the examiner reasonably concluded that it would have been obvious to one of ordinary skill in the art to partially embed in the exterior surface of the implant device of Moumene one or more helical coil springs, and thus achieve the subject matter of claim 11. Suggestion for the above is found in the teaching of Moumene at column 8, lines 32-38, that it is desirable to impart surface characteristics to the implant that enhance the ingrowth of tissue to improve fixation, and the teaching of Bokros at column 1, lines 33-42; column 2, lines 15-19; and column 3, lines 7-14,

of using helical coil springs on the exterior surface of an orthopedic implant to impart precisely controlled porosity to the implant to promote the ingrowth of tissue and/or bone structure thereby creating long-lasting joinder.

Because we find no error in the examiner's rationale in rejecting claim 11 as being obvious in view of Moumene and Bokros, we shall sustain the rejection thereof under 35 U.S.C. § 103. Further, in that appellants have directed that claims 11-17, 43 and 44 should stand or fall together, we shall also sustain the examiner's rejection of claims 12-17, 43 and 44 as being unpatentable over Moumene and Bokros.

We simply do not agree with appellants' argument (main brief, page 6) that Bokros does not disclose partial embedding of the coil springs. In our view, the disclosure of Bokros at column 4, lines 9-12 that "the depth of the channels is preferably near the loop diameter of the spring; *however, in specialized cases it may be appropriate to use a shallow groove or even none at all*" (emphasis added) would be understood by one of ordinary skill in the art as teaching that the springs may be *partially* embedded in the exterior surface of the implant.

Appellants also note (main brief, page 6) that Bokros discloses that the loops/coils of the springs may be sintered to each other, and that this arrangement would be inappropriate in appellants' (and presumably Moumene's) device because it would override the properties of the polymer substrate. This argument is not persuasive for several reasons. First, the argument is not persuasive with respect to claim 11 because claim 11 does not preclude the biocompatible material from being springs whose loops/coils interengage. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982) (arguments predicated on limitations that do not appear in the claims fail at the outset). Second, in contrast to what appellants would apparently have us believe, Bokros does not require that the loops/coils of the individual springs be sintered together. See, for example, the Figures 4-6 embodiment of Bokros where adjacent spring coils are not connected together. Third, in following the teachings of the prior art, the ordinarily skilled artisan is expected to exercise a certain amount of common sense and skill in combining reference teachings (see *In re Sovish*, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985)). Thus, presuming skill on the part of the

ordinarily skilled artisan, as we must, said artisan would not combine the teachings of the references together in a manner that would defeat the very purpose of the primary reference.

The argument that Moumene does not suggest the claim 44 limitation of glass fibers comprising 10% of the implant by volume (main brief, sentence spanning pages 5-6), and the argument that Bokros does not suggest the claim 16 limitation of interstices between nonembedded portions of the coils ranging from 150 to 200 micrometers (main brief, page 6) are noted. Since these limitations do not appear in representative claim 11, they are not persuasive that the examiner erred in so rejecting this claim. *In re Self*, 671 F.2d at 1348, 213 USPQ at 5. In any event, the applied prior art indicates that these parameters are known to be result effective.¹ In our view, it would have been well within the skill of the artisan, at the time the appellants' invention was made, to ascertain from routine experimentation an appropriate percentage of glass fiber reinforcement and an appropriate amount of spring overlap and interleaving to achieve

¹ See, for example, column 7, lines 34-38, of Moumene where it is stated that the short fiber volume ratio may varied to fine tune rigidity and strength of the final product, and column 3, lines 7-14, of Bokros where it is indicated that the amount of overlap and interleaving of adjacent springs may be changed to achieve the desired porosity.

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the desired porosity in the modified implant device of Moumene. Obtaining the claimed glass fiber content of 10% by volume and the claimed interstices between nonembedded portions of the coils ranging from 150 to 200 micrometers are thus viewed as simply the discovery of optimum values of result effective variables. This is especially so in that appellants do not attribute any unexpected result to the claimed values for these variables. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980); *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

In light of the foregoing, we shall sustain the rejection of claims 11-17, 43 and 44 as being unpatentable over Moumene in view of Bokros.

The § 103 rejection of claims 26-33 as being unpatentable over Goble

Independent claim 26 is directed to an intramedullary implant comprising a first piece having an end having a protruding member thereon, a second piece having an end having a cavity formed therein for receiving the protruding member of the

first piece, and means for resisting rotation between the first and second pieces. In addition, claim 26 requires that the rotation resisting means comprises a *flute* on the protruding member and a corresponding *fluted opening* in the cavity.

In rejecting claim 26 as being unpatentable over Goble, the examiner correctly found correspondence between the claimed protruding member of the first piece and the male connector element 14 of Goble, and between the claimed cavity of the second piece and the female connector element 13 of Goble. In rejecting claim 26, we consider that the examiner implicitly determined that it would have been obvious to provide the connector elements 13 and 14 of Goble with means for resisting rotation in view of the teachings of Goble at column 6, lines 36-39; column 8, line 65 through column 9, line 6; and column 9, lines 16-30. Concerning the requirement for a flute on the protruding member and a corresponding fluted opening in the cavity, the examiner has taken the position (final rejection, page 2) that "[f]lutes and fluted openings would have been an obvious modification in order to enhance the rotation resistance discussed in column 6, lines 36-39."

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Rejections based on 35 U.S.C. § 103 must rest on a factual basis. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *Id.*

While the examiner may be correct in his assertion that it would have been obvious to fashion the connector elements of Goble in the form of fluted connections, he has failed to advance any factual basis to show that this is the case. In essence, the examiner's determination of obviousness in this regard is based on nothing more than pure speculation. Moreover, in that appellants' specification states (see page 12, last three lines) that the flutes solve a stated problem of minimizing stress concentrations, this claim limitation may not be dismissed as an obvious matter of design choice without supporting evidence. *Compare In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975) (use of particular connection in lieu of those used in reference

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held to be obvious matter of design choice within the skill in the art *where particular connection solves no stated problem*).

Since the examiner has provided no factual basis for the assertion that it would have been obvious to construct the connector elements of Goble as fluted connectors, the standing rejection of claim 26, as well as claims 27-33 that depend therefrom, as being unpatentable over Goble cannot be sustained.

The § 103 rejection of claims 34-37 as being unpatentable over Goble in view of Bokros

Claim 34 depends from claim 33 and adds that the biocompatible material comprises a coil. Claims 35-37 depend either directly or indirectly from claim 34 and further define the coils. While the Bokros reference relied upon by the examiner for this added feature certainly teaches that biocompatible material of a bone implant may take the form of coils, Bokros does not cure the deficiencies of Goble concerning the fluted connector feature of claim 26 discussed above. Therefore, the standing rejection of claims 34-37 as being unpatentable over Goble in view of Bokros is not sustainable.

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The § 103 rejection of claims 38-42 as being unpatentable over Goble in view of Moumene

Claims 38-42 depend either directly or indirectly from independent claim 26. Claims 38 and 39 further require that the intramedullary implant of claim 26 comprises a polymer having an elastic modulus approximating the elastic modulus of bone, and claims 40-42 further define the polymer. The examiner's reliance on Moumene for its teaching of the details of the polymer material set forth in claims 38-42 is well taken. However, Moumene does not cure the deficiencies of Goble concerning the fluted connector feature of claim 26. Hence, the standing rejection of claims 38-42 as being unpatentable over Goble in view of Moumene also is not sustainable.

The § 103 rejection of claims 18-23 as being unpatentable over Goble in view of Moumene and Bokros

We take up next for consideration the rejection of claims 18, 19 and 20. Claim 19 is a multiple dependent claim that depends from independent claims 11, 43 or 44. As noted earlier, appellants expressly state (main brief, page 5) that the claims grouped under each rejection stand or fall together. Therefore,

in accordance with 37 CFR § 1.192(c)(7), we have selected claim 19 as it depends from claim 11 (hereinafter denominated claim 19/11) as representative of claims 18, 19 and 20.

Claim 19/11 further limits the orthopedic implant of claim 11 by specifying that the claim 11 implant comprises a first piece and a second piece, with the first and second pieces being joined and locked together by an interlocking means. The interlocking means is further defined as comprising a protruding member on the first piece and a cavity on the second piece for receiving the protruding member.

Looking once again to the teachings of the applied references, Goble teaches an implant comprising a first piece 12 and a second piece 11, and interlocking means in the form of a protruding member 14 on the first piece and a cavity 13 on the second piece for receiving the protruding member to join and lock the pieces together. Moumene teaches a bone implant made of thermoplastic material having an elastic modulus approximating the elastic modulus of bone to provide a strong and durable implant, and Bokros teaches a bone implant having a biocompatible material (i.e., coils 32) partially embedded in the surface of the implant (see column 4, lines 9-12) to promote the ingrowth of

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bone. Based on these reference teachings, we are in agreement with the examiner's position to the effect that it would have been obvious to one of ordinary skill in the art to make the implant of Goble of thermoplastic material having an elastic modulus like that of bone, and to partially embed in the surface thereof a biocompatible material, in order to derive the benefits taught by Moumene and Bokros. Thus, we conclude that the reference evidence applied by the examiner is sufficient to establish a *prima facie* case of obviousness of claim 19/11.

The only argument that reasonably appears to be directed against claims 18-20 is found on page 7 of the main brief, wherein appellants argue that claim 18

recites unobvious subject matter for the reasons recited above in Applicants' response to [the] Examiner's rejection of claims 11-17. For the reasons discussed above in conjunction with claims 11, 26-28, 43 and 44, claims 19-23 are not rendered obvious by Goble et al., in view of Moumene et al. and Bokros et al.

Appellants' very general argument in favor of patentability is simply not persuasive that the examiner erred in rejecting claim 19/11. Accordingly, we shall sustain the rejection of representative claim 19/11, as well as claims 18, 19/43, 19/44, 20 that we have grouped with claim 19/11.

Notwithstanding that appellants have directed that we may treat claims 18-23 as a single group standing or falling together, we have elected to consider claims 21-23 separately. Claims 21 and 23 require that the first and second pieces comprise a flute on the protruding member and a corresponding fluted opening in the cavity. Claim 22 requires that the protruding member and the cavity are complementarily tapered. Because the reference evidence adduced by the examiner does not disclose, teach, or suggest these claimed features, we shall not sustain the standing rejection of claims 21-23 under 35 U.S.C. § 103.

Summary

The rejection of claims 11-23, 43 and 44 under 35 U.S.C. § 112, second paragraph, is affirmed.

The rejection of claims 11-17, 43 and 44 as being unpatentable over Moumene in view of Bokros is affirmed.

The rejection of claims 26-33 as being unpatentable over Goble, the rejection of claims 34-37 as being unpatentable over Goble in view of Bokros, and the rejection of claims 38-42 as being unpatentable over Goble in view of Moumene are reversed.

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The rejection of claims 18-23 as being unpatentable over Goble in view of Moumene and Bokros is affirmed as to claims 18-20, but is reversed as to claims 21-23.

The decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

NEAL E. ABRAMS)	
Administrative Patent Judge)	
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